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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,560	12/21/2000	James Peter Fulginiti	ACY33427-00	2516

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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT PAPER NUMBER

1645

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/720,580		FULGINITI ET AL	
	<b>Examiner</b>		<b>Art Unit</b>	
	Ginny Portner		1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 December 2000.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

*HL*

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### DETAILED ACTION

Claims 1-56 are pending. In light of the International Search Report showing the first appearing invention not defining a Special Technical feature making over the prior art, a lack of unity exists and election of an invention is being set forth below.

#### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14,35-37 and 53, drawn to a plurality of polypeptide species and a method of using the polypeptide to induce an immune response.

Group II, claim(s) 15-34,38-50, drawn to a plurality of nucleic acid species, plasmids that comprise the nucleic acids, host cells that comprise the plasmid containing the nucleic acid and a method of producing the encoded polypeptide.

Group III, claim(s) 51-52, drawn to a plurality of antibodies that bind to a plurality of polypeptides and a method of immunizing with an antibody that binds the polypeptide.

Group IV, claim(s) 54, drawn to a method of producing any H.pylori protein utilizing a high copy number plasmid and any Helicobacter pylori nucleotide sequence.

Group V, claim(s) 55-56, drawn to methods of purifying H.pylori polypeptides of any sequence or structure based upon lysing host cells that include inclusion bodies followed by cationic exchange gel chromatograph.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Tomb et al (1997) discloses the first appear invention and therefore lack of unity of invention exists and restriction is proper..

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3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

**Group I:** all polypeptides comprise SEQ ID NO 7, but evidence an overall difference in total molecular weight and amino acid sequence and therefore evidence different structures and biological functions and effects:

A polypeptide of 75 kDa, SEQ ID NO 1

A polypeptide of 75 kDa, SEQ ID No 19

A polypeptide of 77 kDa, SEQ ID NO 2

A polypeptide of 79 kDa, SEQ ID NO 3

A polypeptide of 75 kDa, SEQ ID NO 1, together with a carrier or adjuvant and is conjugated

A polypeptide of 75 kDa, SEQ ID No 19, together with a carrier or adjuvant and is conjugated

A polypeptide of 77 kDa, SEQ ID NO 2, together with a carrier or adjuvant and is conjugated

A polypeptide of 79 kDa, SEQ ID NO 3, together with a carrier or adjuvant and is conjugated

**Group II:** (nucleic acid, plasmid, host cell and method of making a polypeptide of a sequence SEQ ID NO.)

A nucleic acid sequence that hybridizes to Nucleotides 58-2124 of SEQ ID NO 4

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A nucleic acid sequence that hybridizes to nucleotides 1-2070 of SEQ Id NO 21

A nucleic acid that comprises nucleotides 58-2124 of SEQ ID NO 4

A nucleic acid that comprises nucleotides 1-2070 of SEQ Id NO 21

A nucleic acid that encodes amino acids 20-708 of SEQ ID No 1

A nucleic acid that encodes amino acids 1-689 of SEQ ID NO 19

A nucleic acid sequence that hybridizes to nucleotides 61-2223 of SEQ ID NO 5

A nucleic acid sequence encodes amino acids 21-741 of SEQ Id NO 2 or an equivalent amino acid sequence.

A nucleic acid sequence that hybridizes to Nucleotides 61-2235 of SEQ ID NO 6

A nucleic acid sequence that hybridizes to nucleotides 1-2157 of SEQ Id NO 22

A nucleic acid that encodes amino acids 21-745 of SEQ ID No 3

A nucleic acid that encodes amino acids 1-718 of SEQ ID NO 20

**Group III:** An antibody and method of using said antibody, wherein the antibody immunoreacts with:

A polypeptide of 75 kDa, SEQ ID NO 1

A polypeptide of 75 kDa, SEQ ID No 19

A polypeptide of 77 kDa, SEQ ID NO 2

A polypeptide of 79 kDa, SEQ ID NO 3

4. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify

the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The claims are deemed to correspond to the species listed above in the following manner:

A polypeptide of 75 kDa, SEQ ID NO 1 (claims 1(i), 2, 5(i),6,9,13(i),14,35-37, 52-53

A polypeptide of 75 kDa, SEQ ID No 19 (claims 1(i),2,5(i),6,9,13(i),14,35-37,52-53

A polypeptide of 77 kDa, SEQ ID NO 2 (claims 1 (ii),3, 5(ii),7,9,13(ii),14,35-37,52-53

A polypeptide of 79 kDa, SEQ ID NO 3 (claims 1(iii), 4, 5(iii),8,9,13(iii),14,35-37,52-53

A polypeptide of 75 kDa, SEQ ID NO 1, together with a carrier or adjuvant and is conjugated, (claims 10,14,35-36,52-53

A polypeptide of 75 kDa, SEQ ID No 19, together with a carrier or adjuvant and is conjugated (claims 10,14,35-36,52-53

A polypeptide of 77 kDa, SEQ ID NO 2, together with a carrier or adjuvant and is conjugated (claims10,14,35-36,52-53

A polypeptide of 79 kDa, SEQ ID NO 3, together with a carrier or adjuvant and is conjugated,(claims 10, 14,35-36,52-53

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**Group II:** (nucleic acid, plasmid, host cell and method of making a polypeptide of a sequence SEQ ID NO.)

A nucleic acid sequence that hybridizes to Nucleotides 58-2124 of SEQ ID NO 4 (claims 15 (i), 16, 17, 25, 26, 27, 38-50

A nucleic acid sequence that hybridizes to nucleotides 1-2070 of SEQ Id NO 21 (claims 15 (i), 16, 17, 25, 26, 27, 38-50

A nucleic acid that encodes amino acids 20-708 of SEQ ID No 1 (claims 18, 25, 28, 38-50

A nucleic acid that encodes amino acids 1-689 of SEQ ID NO 19 (claims 18, 25, 28, 38-50

A nucleic acid sequence that hybridizes to nucleotides 61-2223 of SEQ ID NO 5 (claims 19-20, 25, 29, 30, 38-50

A nucleic acid sequence encodes amino acids 21-741 of SEQ Id NO 2 or an equivalent amino acid sequence. (claims 21, 25, 31, 38-50

A nucleic acid sequence that hybridizes to Nucleotides 61-2225 of SEQ ID NO 6 (claims 22-23, 25, 32-33, 38-50

A nucleic acid sequence that hybridizes to nucleotides 1-2157 of SEQ Id NO 22 (claims 22-23, 25, 32-33, 38-50

A nucleic acid that encodes amino acids 21-745 of SEQ ID No 3 (claim 24, 25, 34, 38-50

A nucleic acid that encodes amino acids 1-718 of SEQ ID NO 20 (claim 24, 25, 34, 38-50

**Group III:** An antibody and method of using said antibody, wherein the antibody immunoreacts with:

A polypeptide of 75 kDa, SEQ ID NO 1, claim 51(i)

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A polypeptide of 75 kDa, SEQ ID No 19, claim 51(i)

A polypeptide of 77 kDa, SEQ ID NO 2 (claim 51(ii)

A polypeptide of 79 kDa, SEQ ID NO 3(claim 51(iii)

The following claim(s) are generic: no claims in Groups I-III are generic.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp  
April 20, 2005

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